HFI-35

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

SEP - 1 1999

WARNING LETTER

VIA FEDERAL EXPRESS
VIA FACSIMILE

Re: Guideline System 3000 (K970943)

Alan Finkel, Ph.D.
CEO
Axon Instruments, Inc.
1101 Chess Drive
Foster City, California 94404

Dear Dr. Finkel:

The Food and Drug Administration (FDA) has reviewed your website and promotional labeling materials for the Guideline System 3000. This product is manufactured by Axon Instruments, Inc. and is a device as defined within the meaning of section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

Both your website at http://www.axon.com and pages from an ad submitted to the FDA (basically identical to your website heading "GS 3000 Flyer") state that the Guideline System 3000 was developed for use in stereotactic functional neurosurgery/intraoperative microelectrode guidance during pallidotomy, thalamotomy, and the implantation of deep brain stimulators (DBS) for the treatment of Parkinson's Disease and essential tremor. We were also provided with an April 1999 "Dear Doctor" letter on Axon Instruments, Inc. letterhead, which notes that Axon is providing a copy of a CD-ROM entitled "Microelectrode-Guided Neurosurgery." We also have a copy of this CD; a review found that a section entitled "Instrumentation" also contains the same claims noted above.

In the 510(k) application K970943 submitted by Axon, it indicated that the device was to be used during pallidotomies, thalamotomies, epilepsy surgery, and other procedures where appropriate. FDA stated that, unless your firm provided valid scientific evidence to demonstrate the effectiveness of each claim, these claims were to be removed from your labeling, manuals, "Indications for Use" page, as well as promotional material. Axon Instruments subsequently responded that these specific claims had been removed from labeling, manuals, "Indications for Use" page and promotional material.

The Guideline System 3000 has been cleared under section 510(k) of the Act and is intended for recording of intracranial neural activity and for stimulation at subsurface levels of the brain during surgery. The device has not received FDA clearance for the re-inclusion of those additional uses noted above, and found in your promotional materials.

The Guideline System 3000 is adulterated within the meaning of section 501(f)(1)(B) of the Act in that it is a Class III device under section 513(f), and does not have an approved application for premarket (PMA) in effect pursuant to section 515(a), or an approved application for investigational device exemption (IDE) under section 520(g).

The Guideline System 3000 is also misbranded within the meaning of section 502(o) of the Act, in that a notice or other information respecting the modification in the intended use of the device was not provided to FDA as required by 21 CFR 807.81(a)(3)(ii), and the device was not found to be substantially equivalent to a predicate device.

Additionally, according to the ad, the Guideline System 3000 claims to be "FDA Approved," "...the first instrument of its kind to gain both US FDA approval...," and "...cleared by the FDA for distribution in the USA." (This information was also noted on your website). The CD states under "Warnings!" that "the Guideline System 3000, manufactured by Axon Instruments, is the only equipment currently available that is FDA approved." 21 CFR 807.97 specifically provides that any representation that creates an impression of official approval because of complying with the premarket notification regulations is misleading and constitutes misbranding.

This letter is not intended to be an all-inclusive list of deficiencies associated with your Guideline System 3000. It is your responsibility to ensure adherence to each requirement of the Act and Federal regulations. The specific violations noted in this letter may represent practices used in other promotion or advertising materials used by your firm. You are responsible for investigating and reviewing these materials to assure compliance with applicable regulations.

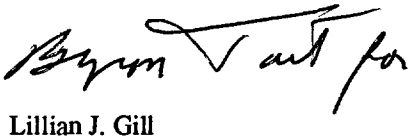
You should take prompt action to correct these violations. Failure to promptly correct these deviations may result in regulatory action being initiated by FDA without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil penalties.

Please notify this office, in writing, within 15 working days of receipt of this letter, outlining the specific steps you have taken to correct the cited violations. Your response should also include all steps being taken to address misleading information currently in the market place and actions to prevent similar violations in the future. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

Your response should be sent to Ms. Patricia L. Jahnes, Consumer Safety Officer, Promotion and Advertising Policy Staff (HFZ-300), Office of Compliance, Center for Devices and Radiological Health, 2098 Gaither Road, Rockville, Maryland 20850.

A copy of this letter is being sent to FDA's San Francisco District Office. Please send a copy of your response to the District Director, Food and Drug Administration, 1431 Harbor Bay Parkway, Alameda, California 94502-7070.

Sincerely yours,



Lillian J. Gill
Director
Office of Compliance
Center for Devices and
Radiological Health